K112538

MAR 2 9 2012

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	August 30, 2011	
Device:	Trade Name:	ACE Cholesterol Reagent
	Classification:	Class 1
	Common/Classification Name:	Enzymatic Esterase-Oxidase, Cholesterol (21 C.F.R. § 862.1175) Product Code CHH
	Trade Name:	ACE HDL-C Reagent
	Classification:	Class 1
	Common/Classification Name:	LDL & VLDL Precipitation, Cholesterol Via Esterase-Oxidase, HDL (21 C.F.R. § 862.1475) Product Code LBS
	Trade Name:	ACE LDL-C Reagent
	Classification:	Class 1
	Common/Classification Name:	System, Test, Low Density, Lipoprotein (21 C.F.R. § 862.1475) Product Code MRR
	Trade Name:	ACE Triglycerides Reagent
	Classification:	Class 1
	Common/Classification Name:	Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides (21 C.F.R. § 862.1705) Product Code CDT

Predicate Devices:	Manufacturer for reagent system predicates: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Reagents (K931786, K971526, K991733)
Device Descriptions:	In the ACE Cholesterol Reagent assay, cholesterol esters in serum or heparin plasma are completely hydrolyzed by cholesterol esterase to free cholesterol and free fatty acids. The cholesterol liberated by the esterase, plus any endogenous free cholesterol, are both oxidized by cholesterol oxidase to yield hydrogen peroxide. The hydrogen peroxide then acts to oxidatively couple p-hydroxybenzoic acid and 4-amin-oantipyrine in a reaction catalyzed by peroxidase, producing a red colored quinoneimine complex which absorbs strongly at 505 nm. The amount of chromogen formed, determined by measuring the increase in absorbance, bichromatically at 505 nm/647 nm, is directly proportional to the cholesterol concentration in the sample. The HDL-C Assay utilizes two reagents, the second containing a unique detergent. This detergent solubilizes only the HDL lipoprotein particles, thus releasing HDL cholesterol to react with the cholesterol esterase and cholesterol oxidase, in the presence of a chromogen to produce color. The detergent also inhibits the reaction of the cholesterol enzymes with LDL, VLDL and chylomicron lipoproteins by adsorbing to their surfaces. The amount of chromogen formed, determined by measuring the increase in absorbance bichromatically at 592/692 nm, is directly proportional to the HDL cholesterol concentration in the sample. In the ACE LDL-C Reagent assay, detergent 1 solubilizes non-LDL lipoprotein particles (HDL, VLDL and chylomicrons) and releases cholesterol. The cholesterol is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. In a second reaction, detergent 2 solublizes the remaining LDL particles and forms peroxide, via the enzymes cholesterol esterase and cholesterol oxidase. The peroxide, in the presence of peroxidase and two peroxidase sub-strates, 4-aminoantipyrine and DSBmT, results in a purple-red color. The amount of color formed, determined by measuring the increase in absorbance bichromatically at 544/692 nm, is directly proportional to the LDL cholesterol concentration in the sample. In the ACE Triglycerides Reagent assay, triglycerides in serum or heparin plasma are hydrolyzed by lipase to form glycerol and free fatty acids. In the presence of adenosine triphosphate (ATP) and glycerol kinase, the glycerol is converted to glycerol-1-phosphate and the ATP to adenosine diphosphate. Glycerol-1-phosphate is oxidized by glycerol phosphate oxidase to yield hydrogen peroxide. The hydrogen peroxide then acts to oxidatively couple p-chlorophenol and 4-aminoantipyrine in a reaction catalyzed by peroxidase, producing a red colored

	quinoneimine complex which absorbs strongly at 505 nm. The amount of chromogen formed, determined by measuring the increase in absorbance bichromatically at 505 nm/692 nm, is directly proportional to the triglycerides concentration in the sample.
Intended Use:	Indications for Use: ACE Cholesterol Reagent is intended for the quantitative determination of cholesterol in serum and lithium heparin plasma using the ACE and ACE Alera Clinical Chemistry Systems. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. ACE HDL-C Reagent is intended for the homogeneous, quantitative determination of HDL cholesterol (HDL-C) in serum and lithium heparin plasma using the ACE and ACE Alera Clinical Chemistry Systems. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. ACE LDL-C Reagent is intended for the quantitative determination of low density lipoprotein cholesterol (LDL-C) in serum and lithium heparin plasma using the ACE and ACE Alera Clinical Chemistry Systems. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. ACE Triglycerides Reagent is intended for the quantitative determination of triglycerides in serum and lithium heparin plasma using the ACE and ACE Alera Clinical Chemistry Systems. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

<table>
<tr><td>Technological Characteristics:</td><td>The ACE Cholesterol Reagent is composed of a single reagent bottle. The reagent contains 4-aminoantipyrine, p-hydroxybenzoic acid, cholesterol oxidase, cholesterol esterase and peroxidase.

The ACE HDL-C Reagent is composed of two reagent bottles (Buffer and Color Reagent). The reagents contain Good's buffer, cholesterol oxidase, peroxidase, N,N-bis(4-sulphobutyl)-m-toluidine-disodium salt, ascorbic oxidase, cholesterol esterase 4-aminoantipyrine and a detergent.

The ACE LDL-C Reagent is composed of two reagent bottles (Buffer and Color Reagent). The reagents contain MES Buffer (pH 6.3), detergent 1, cholesterol esterase, cholesterol oxidase, peroxidase, 4-aminoantipyrine, ascorbic acid oxidase, detergent 2 and N,N-bis(4-sulphobutyl)-m-toluidine-disodium salt.

The ACE Triglycerides Reagent is composed of a single reagent bottle. The reagent contains aminoantipyrine, adenosine 5'-triphosphate, p-chlorophenol, glycerol phosphate oxidase, lipase, peroxidase and glycerol kinase.</td></tr>
<tr><td>Performance Data:</td><td>Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE and ACE Alera Clinical Chemistry Systems included matrix comparison data:

<u>ACE Cholesterol Reagent</u>

<u>ACE Clinical Chemistry System</u>

A study was performed on the ACE Clinical Chemistry System by running 102 cholesterol determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin plasma tubes. Five paired serum/plasma samples were spiked with lipoprotein cholesterol concentrate. The serum results ranged from 40 to 568 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y):

<table>
<tr><td>Regression Equation</td><td>y = 0.985x - 1.7</td></tr>
<tr><td>Correlation Coefficient</td><td>0.9947</td></tr>
<tr><td>Std. Error Est.</td><td>9.6</td></tr>
<tr><td>Confidence Interval Slope</td><td>0.965 to 1.005</td></tr>
<tr><td>Confidence Interval Intercept</td><td>-5.7 to 2.3</td></tr>
</table>

<u>ACE Alera Clinical Chemistry System</u>
A study was performed on the ACE Alera Clinical Chemistry System by running 103 cholesterol determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin</td></tr>
</table>

plasma tubes. Six paired serum/plasma samples were spiked with lipoprotein cholesterol concentrate. The serum results ranged from 42 to 577 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y):

Regression Equation	y = 0.994x - 2.5
Correlation Coefficient	0.9934
Std. Error Est.	11.5
Confidence Interval Slope	0.971 to 1.016
Confidence Interval Intercept	-7.0 to 2.1

ACE HDL-C Reagent

ACE Clinical Chemistry System

A study was performed on the ACE Clinical Chemistry System by running 101 HDL determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin plasma tubes. The serum results ranged from 6 to 120 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y):

Regression Equation	y = 1.015x - 0.6
Correlation Coefficient	0.9884
Std. Error Est.	3.4
Confidence Interval Slope	0.984 to 1.045
Confidence Interval Intercept	-2.1 to 0.8

ACE Alera Clinical Chemistry System

A study was performed on the ACE Alera Clinical Chemistry System by running 100 HDL determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin plasma tubes. The serum results ranged from 7 to 123 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y):

Regression Equation	y = 0.989x + 0.4
Correlation Coefficient	0.9874
Std. Error Est.	3.5
Confidence Interval Slope	0.957 to 1.020
Confidence Interval Intercept	-1.2 to 1.9

ACE LDL-C Reagent

ACE Clinical Chemistry System

A study was performed on the ACE Clinical Chemistry System by running 99 LDL determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin plasma tubes. Four paired serum/plasma samples were spiked with LDL cholesterol concentrate. The serum results ranged from 9 to 460 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y):

Regression Equation	y = 1.008x - 2.6
Correlation Coefficient	0.9954
Std. Error Est.	7.3
Confidence Interval Slope	0.989 to 1.028
Confidence Interval Intercept	-5.0 to -0.2

ACE Alera Clinical Chemistry System

A study was performed on the ACE Alera Clinical Chemistry System by running 99 LDL determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin plasma tubes. Four paired serum/plasma samples were spiked with LDL cholesterol concentrate. The serum results ranged from 9 to 464 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y):

Regression Equation	y = 0.995x - 1.3
Correlation Coefficient	0.9954
Std. Error Est.	7.2
Confidence Interval Slope	0.976 to 1.014
Confidence Interval Intercept	-3.7 to 1.0

ACE Triglycerides Reagent

ACE Clinical Chemistry System

A study was performed on the ACE Clinical Chemistry System by running 101 triglycerides determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin plasma tubes. Five paired serum/plasma samples were spiked with triglycerides. The serum results ranged from 39 to 887 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y):

	<table><tr><td>Regression Equation</td><td>y = 1.005x - 7.9</td></tr><tr><td>Correlation Coefficient</td><td>0.9977</td></tr><tr><td>Std. Error Est.</td><td>11.1</td></tr><tr><td>Confidence Interval Slope</td><td>0.991 to 1.019</td></tr><tr><td>Confidence Interval Intercept</td><td>-11.1 to -4.7</td></tr></table> <u>ACE Alera Clinical Chemistry System</u> A study was performed on the ACE Alera Clinical Chemistry System by running 101 triglycerides determinations in singlicate on paired samples drawn from the same patients in serum and lithium heparin plasma tubes. Five paired serum/plasma samples were spiked with triglycerides. The serum results ranged from 38 to 884 mg/dL. Linear regression analysis (Deming) yielded the following results (serum = x, plasma = y): <table><tr><td>Regression Equation</td><td>y = 1.007x - 7.4</td></tr><tr><td>Correlation Coefficient</td><td>0.9973</td></tr><tr><td>Std. Error Est.</td><td>11.8</td></tr><tr><td>Confidence Interval Slope</td><td>0.992 to 1.021</td></tr><tr><td>Confidence Interval Intercept</td><td>-10.8 to -4.0</td></tr></table>
Conclusions:	Based on the foregoing data, the devices are safe and effective. These data also indicate substantial equivalence for the use of lithium heparin plasma sample collection tubes to the use of serum sample collection tubes on the ACE and the ACE Alera Clinical Chemistry Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Alfa Wassermann Diagnostic Technologies, LLC
c/o Hyman Katz
4 Henderson Drive
West Caldwell, NJ 07006

MAR 2 9 2012

Re: Re: k112538
Trade Name: ACE Cholesterol Reagent, ACE HDL-C Reagent, ACE LDL-C Reagent, and ACE Triglyceride Reagent
Regulation Number: 21 CFR §862.1175
Regulation Name: Cholesterol Test Reagent
Regulatory Class: Class I, meets limitations per 21CFR862.9(c)(4)
Product Codes: CHH, LBS, MRR, CDT
Dated: March 19, 2012
Received: March 20, 2012

Dear Dr. Katz,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112538

Device Name: ACE Cholesterol Reagent

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Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112538

Indications for Use

510(k) Number (if known): K112538

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112538